

REMARKS

Claims 5-21 are presently pending in the application.

At the outset, the Examiner's attention is directed to the Supplemental Information Disclosure Statement submitted herewith, in which Applicant resubmits the foreign language references originally submitted on October 5, 2005, but which were crossed off the PTO-1449 form as not considered by the Examiner. All of these references now have English language comments, either in the Background Section of the application, in English language versions of the International Search Report or International Preliminary Examination Report, in the attached English language Abstracts, or in the text of the IDS. Accordingly, consideration of the references and initialing by the Examiner are respectfully requested.

The specification has been amended to correct or make clear certain terms used in the application. In particular, paragraph [0002] has been amended to refer to the alternate term for "maturing," namely "ripening"; see for example the Robinson reference relied upon by the Examiner. Further, the term "diminution" has been corrected to "comminution," since the latter term more accurately reflects what is being done in the sausage making process and was intended to be described. Thus, "diminution" is defined as the act, fact or process of diminishing, lessening, reduction, whereas "comminution" means pulverizing, trituration, dividing into small parts. See *The Random House Dictionary of the English Language*, Second Edition unabridged (1987).

The latter meaning is evident from the context of paragraphs [0015] and [0038] of the published application, which refer to processing the lean meat in a cutter and chopping the meat in a cutter to a fine granular state. Moreover, the word in the German priority application from which this term was translated is "Zerkleinerung," which is properly translated as disintegration, comminution, size reduction. See Richard Ernst, *Wörterbuch der industriellen Technik* (Dictionary of Industrial Technology), Brandstetter Verlag, Weisbaden (1989). Accordingly, no new matter has been added and entry of the amendments to the specification is respectfully requested.

Independent claim 5 and claim 6 have also been amended to change "diminished" to "comminuted" for the reasons discussed above. In addition, the invention has been clarified in

claim 5 to provide that the method is one of accelerating the microbiological maturing process (i.e., ripening) in which the raw sausage meat is allowed to mature microbiologically after addition of the at least one material selected from folic acid and folate. These amendments are supported, for example, in paragraphs [0014], [0015], [0018], [0023] and [0024] of the published application. Claims 6, 9, 10 and 12-17 have been amended to make minor formal corrections to the claims and to conform the claims to amended claim 5.

Further, new claims 19-21 have been added to claim further features or embodiments of the invention, and are supported, for example, at paragraphs [0026] (claim 19), [0015] (claim 20), [0025], [0035] and [0037] (claim 21). Accordingly, no new matter has been added by the claim amendments, and entry is respectfully requested.

In the Office Action dated March 18, 2009, the Examiner rejected claims 5-18 under 35 U.S.C. § 103(a) as being unpatentable over Robinson ("Fermented Meat Products" in *Encyclopedia of Food Microbiology*) in view of Rader ("Folic Acid Fortification, Folate Status, and Plasma Homocysteine") and as evidenced by Kerry et al. ("Quality Control of Fermented Meat Products" in *Meat Processing-Improving Quality*). The Examiner contends that Robinson discloses a method of making a semi-dry sausage comprising the steps of providing minced meat, mixing the minced meat with additives, stuffing the mixture into natural or artificial casings, and storing the sausage for 9-23 days at a particular relative humidity and temperature. The Examiner acknowledges that Robinson does not explicitly disclose adding about 4 mg. to about 25 mg. per kilogram of meat of a material selected from folic acid and folate.

However, the Examiner contends that Rader teaches folic acid as a known additive in foods as a fortification to reduce the risk of neural tube birth defect (NTD) occurring during pregnancy and the risk of vascular disease. Rader also teaches the addition of folic acid to enriched cereal-grain products becoming mandatory in the United States on January 1, 1998 at a level of 140 µg folic acid/100 g of cereal-grain product. The Examiner further contends that Kerry et al. evidences that the improvement of the nutritional value of meat products has been tried for years.

The Examiner therefore concludes that it would have been obvious to one skilled in the art to fortify the semi-dry sausage of Robinson with folic acid or folate, as taught by Rader, in order

to increase the intake of folic acid or folate and reduce the risk of NTD-pregnancies and vascular disease. The Examiner acknowledges that Rader teaches the addition of folic acid to cereal-grain, but takes the position that folic acid concentration is a result-effective variable because changing it would clearly affect the type of product obtained. The Examiner therefore concludes that it would have been obvious to one skilled in the art to utilize appropriate folic acid concentration within the scope of the present claims to produce desired end results.

In addition, in the Advisory Action dated September 16, 2009, the Examiner has further cited an Abstract of Russian Patent RU 2213493 C2 of Aslanova et al. for "Meat-Based Canned Food Product for Feeding Pregnant and Suckling Women" ("Aslanova"). While this reference has not yet been applied to the claims, the Examiner could presumably use the Aslanova patent to replace Rader and/or Kerry et al in the above rejection.

The above rejection is respectfully but strenuously traversed for the reasons set forth in detail below. It is requested that the Examiner ignore the arguments made by Applicant's prior attorney of record in response to previous Office Actions, except to the extent that they are repeated below, since the previous arguments included a number of errors which Applicant does not wish to rely upon.

In the Advisory Action dated September 16, 2009, the Examiner argues that Applicant's previous arguments are not commensurate in scope with the claims, in that Applicant argues that adding the folic acid or folate in the defined amount to raw sausage meat results in improved and accelerated ripening of the final product and, during such ripening, in an enzymatic fermentation which in turn preserves the sausage. The Examiner contends that claim 1 (sic claim 5) is directed to raw sausage meat, while Applicant's arguments are directed to ripened sausage.

While Applicant does not necessarily agree with the Examiner's arguments and characterizations of previous claims, independent claim 5 has been amended to clarify that the method is directed to accelerating the microbiological maturing process in the making of raw sausage. Therefore, the claims are now commensurate in scope with Applicant's arguments.

The Examiner seems to misunderstand the term "raw sausage." Thus, even though the raw sausage meat is matured or ripened, the ripened sausage may still be referred to as "raw sausage" in the sense that it is not cooked. See, e.g., paragraph [0024], last sentence, of the

published application. Note also that Robinson refers to such sausage as “fermented sausage.” Thus, fermentation and drying of the sausage constitute the maturing or ripening which is necessary to make the final semi-dry or dry sausages edible.

In any event, the present claims clarify that the method is directed to accelerating the microbiological maturing of the raw sausage by adding a specified quantity of folic acid and/or folate and allowing the raw sausage to mature after addition of the folic acid and/or folate. None of the prior art teaches or suggests such a process.

While Robinson is directed to the ripening of raw sausage meat by fermentation and drying and does indeed mention the addition of various additives to the minced or comminuted meat, such as nitrate, nitrite, NaCl, ascorbate, and seasonings, such as sugar, garlic, pepper, there is no mention of the addition of folic acid or folate to the method described in Robinson. The only acceleration of the ripening process suggested in Robinson is the rapid fermentation of semi-dry sausages produced in the United States at an elevated temperature, either without drying or with a short period of drying followed by cooking at the end of fermentation. In contrast, traditional Mediterranean products have a slow ripening process which allows the development of molds and yeasts on the surface, and fermentation in northern and central Europe is generally combined with smoking, which shortens the drying period and prevents the development of yeasts and molds. See Robinson, page 745, top of left hand column.

The Examiner acknowledges that Robinson does not disclose adding about 4 mg to about 25 mg of folic acid and/or folate per kilogram of meat, but argues that it would have been obvious to fortify the semi-dry sausage of Robinson with folic acid or folate as taught by Rader. Rader teaches the required fortification of cereal-grain products in the United States at a level of 140 µg folic acid per 100 g cereal-grain product. This translates to 1.4 mg per kilogram of cereal-grain product.

Rader has nothing to do with a method for accelerating the microbiological maturing of raw sausage meat. Rader is directed exclusively to fortifying cereal-grain products. Moreover, Rader does not suggest the fortification of meats with folic acid or folate or any other fortifying material. Therefore, Robinson and Rader are not properly combinable because there is no rational, articulated reason for one skilled in the art to have used the folic acid/folate, reported by

Rader for cereal-grain products, in the processing of raw sausage meat.

In any event, the level of folic acid fortification of the cereal-grain product (1.4 mg folic acid per kilogram of cereal-grain product) reported by Rader is far below the minimum amount of folic acid or folate which is used in the presently claimed process. Therefore, even if Rader were properly combinable with Robinson, which Applicant does not agree, the combination of Robinson and Rader still fails to teach or suggest any of the presently claimed invention, including accelerating the microbiological maturing of the raw sausage meat, adding about 4.5 mg to about mg of folic acid and/or folate to the raw sausage meat, and allowing the raw sausage to mature microbiologically after addition of the folic acid or folate. Moreover, the level of folic acid and/or folate decreases during the maturing process (see paragraph [0034] of the published application), and the amount which may be left as fortification in the final product is not linear over time or predictable. Therefore, the combination of Rader and Robinson totally fails to teach or suggest the presently claimed invention.

The addition of Kerry et al fails to make up for any of the deficiencies of Robinson and Rader or the combination thereof. The Examiner cites Kerry et al solely for the proposition of improving the nutritional value of meat products by fortification. Such fortification and improvement of nutritional value of meat products is already acknowledged at paragraphs [0004]-[0012] of the publication of the present application. Neither Kerry et al nor the various prior art cited in the Background Section of the present application teaches or suggests the addition of folic acid or folate to raw sausage meat, and none teaches or suggests that folic acid and/or folate can be used to accelerate the microbiological maturing process of raw sausage meat. Accordingly, the rejection of the claims is improper and should be withdrawn.

Even considering the Aslanova Russian patent cited by the Examiner in the Advisory Action, this reference, if indeed it constitutes prior art (which Applicant does not concede), still does not teach or suggest the presently claimed invention, taken alone or in combination with any of the other prior art relied upon by the Examiner. Thus, according to the Abstract of Aslanova, folic acid is one of many components of a canned meat product which is "prepared on the basis of metabolic features of women's organism during pregnancy or baby suckling." Thus, this is merely another teaching of food fortification. At least the Abstract of the patent does not state how much folic acid is present, and there is no suggestion that the folic acid is used to accelerate

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microbiological maturing of the meat product. Accordingly, Aslanova adds nothing to the other references relied upon by the Examiner (Robinson, Rader and Kerry et al), except the presence of folic acid in a meat product.

In sum, the prior art relied upon by the Examiner, taken either alone or in combination, totally fails to teach or suggest the presently claimed invention or any of the essential steps thereof. In fact, the only step of independent claim 5 taught by the prior art relied upon is the comminution of raw sausage meat, as taught by Robinson. This is of course conventional in the production of raw sausage meat products, and it is the remaining steps of and overall method that are new and non-obvious.

Finally, Applicant notes that the European patent application counterpart of the present application has been granted without Office Action. While Applicant recognizes that the actions of foreign patent offices are not binding on the USPTO, this allowance is nevertheless evidence that the present application is considered by others to be inventive or non-obvious.

Accordingly, reconsideration and withdrawal of the rejections and an early notice of allowance are respectfully requested.

Respectfully submitted,

Marcus J. SEEWALD

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By: 

William W. Schwarze
Registration No. 25,918
PANITCH SCHWARZE BELISARIO & NADEL LLP
One Commerce Square
2005 Market Street, Suite 2200
Philadelphia, PA 19103-7086
Telephone: (215) 965-1330
Direct Dial: (215) 965-1270
Facsimile: (215) 965-1331
E-Mail: wschwarze@panitchlaw.com

WWS/rdb

Enclosures: Request for Continued Examination (RCE) under 37 C.F.R. § 1.114
Petition for Revival under 37 C.F.R. § 1.137(b)
Supplemental Information Disclosure Statement